CHANGES TO IRB SOP
APRIL 2009 (VERSION 7.2)

Note: All text changes are indicated in **bold.**

Section/Page Number	Summary of Changes
Coversheet	1. Version Changed From 7.1 to 7.2 2. Version Date Changed from 2/10/2009 to xx/xx/2009
Glossary	1. The following terms have now been added and defined in the glossary: • Co-investigator • Principal Investigator 2. The following term has been removed from the glossary: • VAPHS investigator/VAPHS research staff
Page 8; Section 4.E, 1st paragraph	1. Added the following language: **For studies deemed to be greater than minimal risk, the PI must have a significant physical presence at the VAPHS- either related to clinical responsibilities or in relation to other research activities. Residents, fellows, and trainees may not serve as Principal Investigators.**
Page 10; Section 4.E, PI Responsibilities, Item 15	1. New item added. **The PI must ensure that the most recent IRB-approved consent form is used within 5 business days of IRB approval. The previously approved version may be used during this timeframe provided that it has not expired and that there has not been an indication by the IRB that use of the previous version is unacceptable and that it must be voided immediately. Note: the approval is documented on each page of the consent form, as indicated by a stamp that includes the consent version date, date of approval, and date of expiration.**
Page 10; Section 4.E, PI Responsibilities, Item 18	1. Revised sentence regarding time period for completion of human subjects and good clinical practice training- removing "between October 1 and October 31." Revised sentence to now read: The PI must have completed training in human subjects protection as well as good clinical practice as specified by the IRB and must renew such certification annually.

Page 11 & 12; Section 4.E, PI Responsibilities	1. Removed repeated references to website. Added one paragraph which now reads as follows: **The VAPHS Research Website is available to all investigators, staff, employees, and the public (http://www.vaphs.research.med.va.gov/). The VAPHS IRB SOP's and other relevant policies are posted on this website. Updated instructions to investigators for initial submissions, continuing review submissions, and for submitting amendments /modifications are also available on the Research website or can be obtained by contacting the Research Office at 412-954-5381.**
Page 12, Section 4.F	1. Section title now changed to: **Responding to and/or** Appealing IRB Determinations (38 CFR 16.109(d)). 2. Section text significantly revised to now provide instructions for submitting a response or appeal to IRB determinations, including the use of a detailed memo.
Page 23, Section 6.A	1. Language regarding the storage of research records revised in conjunction with VHA Handbook 1200.05 clarification. Section now reads: All active records are maintained by the IRB staff and are located in the research office in locked cabinets. All non-active records are maintained by the Records Control Officer and are secured in the research record archives. All records will be retained **until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RSC 10-1).**
Page 35, Section 7.A	1. Removed the following sentence Each committee meets at least 11 times per year.
Page 57, Section 8.H	1. Removed the following paragraph: Under certain circumstances providers may inform patients that they may qualify for studies at outside institutions. These studies must provide experimental interventions that are not available at VAPHS and all treatments available at VAPHS have been exhausted. The provider should not inform patients of such studies if the provider has a potential conflict of interest, including financial interests in the study in question. If these criteria are met the provider may inform the patient about the study but may not refer the patient to participate in the study. The patient may be given contact information regarding the study, but appointments may not be made for the patient, and the patient may not be given recruitment flyers or other advertisements unless

	approved by the VAPHS IRB. 2. Added the following sentence: **Please see the Guidance on Engagement and Referral of VAPHS Patients for Research Studies Conducted by non-VAPHS Entities for additional information.**
Page 60, Section 8.I	1. Paragraph regarding research involving children revised to broaden the categories of research that will be permissible at VAPHS. 2. Paragraph regarding research involving children revised to read as follows: Research involving children. The VA is authorized to care for veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to veterans and is not authorized to care for the offspring of Veterans. Therefore, research involving children shall not be conducted by VAPHS investigators while on official duty or at VA or approved off-site facilities **unless a waiver has been granted by the Chief Research and Development Officer (CRADO) and that research is deemed no greater than minimal risk. Any VA research which proposes to involve children must include an appropriate justification for the inclusion of children, including how the results of such research are applicable to the veteran population. Each proposal will be considered by the VAPHS IRB on a case-by-case basis.**
Page 61, Section 8.L	1. 1st Paragraph revised to read as follows: **Regulatory audits are completed by the Research Compliance Officer(s) in accordance with VHA Directive 2008-064, Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations and Policies. Audit reports and investigator responses are** reviewed by the Research Compliance Committee (see Appendix D). However, the IRB has the authority to request **a "for-cause" audit** based on submissions to or findings of the IRB. Results of these audits will be forwarded to the full IRB for review and appropriate action. The IRB also has the authority to review the results of audits managed by the Research Compliance Committee.
Page 69, Section 9.A	1. The following language has been added to describe procedures related to sponsor safety reports received prior to IRB approval. **Note: These requirements outlined below apply to those adverse events that occur after the IRB has approved the project. External safety reports received from study sponsors prior to IRB approval should be reviewed by the Principal**

	Investigator to ensure that there are not new safety concerns that should be considered by the IRB during its review. In particular, such reports should be reviewed by the PI to determine whether the event is already described (i.e., is expected) or not (i.e., is unexpected) and whether the event is related to the research or not. Any events determined to be unexpected and related must be reported with the initial submission. Those determinations made after the initial submission, but prior to IRB approval, must be submitted with the response to comments. The Adverse Event Reporting Form should not be submitted in these cases. However, all safety reports should be documented on the External Adverse Event Log.
Page 100, Section 15.C	1. 1st paragraph of this section has been revised to indicate that the VAPHS IRB will allow certain types of research involving children at its discretion. 2. The specific language is as follows: VAPHS considers any person under the age of 18 years as a child. **The VAPHS will not conduct research involving children with the exception of minimal risk studies which in the opinion of the VAPHS IRB demonstrate a potential benefit to the veteran population. If a project includes children** participants, approval is required from the Chief Research and Development Officer in addition to review and oversight by the VAPHS IRB, in accordance with DHHS regulations 45 CFR 46, Subpart D.
Page 107, Section 15.L	1. Sub-section on children revised to broaden the type of research involving children that will be permitted at VAPHS. 2. Language revised as follows: **The only types of research involving children permissible at the VAPHS would be minimal risk studies involving children that, in the opinion of the IRB, demonstrate a potential benefit to the veteran population.** If an investigator wishes to perform research involving children, a waiver from the CRADO must be obtained prior to initiating the research.
Page 111-124, Section 17	1. Formatting corrected
Throughout Document	1. All references to VHA Handbook 1200.5 have been changed to 1200.05 to reflect the new numbering system for VHA Handbooks.